

REMARKS

Status of the Claims.

Claims 1-8 are pending with entry of this amendment, claims 9-10 being canceled and no claims being added herein. Claim 1 is amended herein. This amendment introduces no new matter. Support is replete throughout the specification (*e.g.*, in the claims as originally filed, at page 15, lines 24-27, and the like).

Election/Restriction.

Pursuant to a restriction requirement made final, Applicants cancel claims 9-10 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Claim objections.

Claim 1 was objected to because it contained improper periods in parts thereof. Claim 1 is amended herein to remove such periods thereby obviating this objection.

35 U.S.C. §101.

Claims 1-3 were rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. In making this rejection the Examiner alleged that the claimed invention because the claimed do not require performance of a result outside of a computer or represent some type of physical transformation which is concrete or tangible or a concrete, tangible and useful invention. Applicants traverse by amendment and argument.

Claim 1, as amended herein recites:

1. A method of determining statistical significance of disease incidence, said method comprising:
 - a) selecting at least one founder from a computerized genealogical database;
 - b) identifying a very large family from the founder in said computerized genealogical database;
 - c) linking the very large family to a disease database;
 - d) determining an incidence of disease by calculating which and how many individuals within the very large family have the disease;
 - e) comparing the incidence of disease in the very large family to a general population incidence of disease; and

f) assessing a statistical significance of the disease incidence in the very large family and presenting a measure of said statistical significance on a display or printout.

MPEP §2106(IV)(b) at page 2100-16 teaches that in "[a] method of using a computer processor to analyze electrical signals and data representative of human cardiac activity . . ." the data is an intangible representations of physical activity, i.e., human cardiac activity. The transformation occurs when the activity is measured and an electrical signal is produced. The MPEP concludes "This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack." and thus meets the requirements of 35 U.S.C. §101.

In the instant case, claim 1, as amended herein, provides a method that involves selecting at least one founder from a computerized genealogical database, identifying a very large family from the founder, linking the very large family to a disease database, and determining an incidence of disease . . .

The representation of a founder in a genealogical database (the data) is an intangible representation of a physical person having particular physical and genealogical characteristics. The generation of a very large family, the linking of the family to a disease database and the determining an incidence of disease is a transformation of this data representing real physical people. The final result "assessing a statistical significance of the disease incidence in the very large family and presenting a measure of said statistical significance on a display or printout" **has real world value** in predicting vulnerability to the disease state of a particular population.

The present independent claim is thus completely analogous to the illustrative claim presented in the MPEP and clearly meets the requirements of 35 U.S.C. §101. Accordingly the rejection on these grounds should be withdrawn.

35 U.S.C. §102.

Claims 1-8 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Palsson (US 6,524,797). Applicants traverse.

Presently pending claim 1 reads:

1. A method of determining statistical significance of disease incidence, said method comprising:

- a) selecting at least one founder from a computerized genealogical database;
- b) identifying a very large family from the founder in said computerized genealogical database;
- c) linking the very large family to a disease database;
- d) determining an incidence of disease by calculating which and how many individuals within the very large family have the disease;
- e) comparing the incidence of disease in the very large family to a general population incidence of disease; and
- f) assessing a statistical significance of the disease incidence in the very large family and presenting a measure of said statistical significance on a display or printout.

Palsson provides methods of identifying therapeutic compounds in a genetically defined setting. Palsson neither discloses nor teaches or suggests methods of determining statistical significance of disease incidence as recited both in the preamble in element "f" of the claim.

In addition, the method of claim 1 involves:

selecting at least one founder from a computerized genealogical database
identifying a very large family from the founder in that database; and
linking that very large family to a disease database.

Palsson fails to disclose, teach, or suggest the selection of one or more founders from a computerized genealogical database, the identification of a very large family from that founder in that database, or the linking of that very large family to a disease database.

Indeed, the only reference to a database whatsoever in Palsson is to a database of diseases. Moreover, the use of the database referenced in Palsson is simply to identify disease states known to have a genetic component.

The invention is particularly amenable to identifying therapeutic compounds potentially effective against pathological conditions with a known hereditary component, and which affect a significant proportion of the population, such as, for example, asthma, cardiovascular disease, many types of cancer, schizophrenia, dementia, obesity, and diabetes. The invention can also be practiced with respect to rarer or monogenetic diseases such as, for example, diseases described in the Online Mendelian Inheritance in Man database (Center for Medical Genetics, Johns Hopkins University (Baltimore, Md.) and National Center for Biotechnology Information, National Library of Medicine (Bethesda, Md.) (1998)). [emphasis added] (col. 3, line 58, to col. 4, line 4)

Review of the paragraph quoted above and the issued patent shows that Palsson simply **does not** teach the selection of a founder from such a database, identification of a very large family from the rounder in that database or linking of that very large family to a disease database.

Indeed, the only selection taught by Palsson, is the simple selection of a disease state known to have a genetic component. Accordingly, Palsson fails to provide all the limitations of the presently claimed method and the rejection of claims 1-8 under 35 U.S.C. §102(e) on these grounds should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 267-4161.

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Respectfully submitted,



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